

### REMARKS

Claims 1-2, 4 and 6-8 are pending and claims 1 and 4-7 are rejected in the above-identified application.

While the Examiner has rejected claims 3 and 5 in the outstanding December 8, 2006 Office Action, applicants respectfully point out that claims 3 and 5 were cancelled as per the December 16, 2005 Preliminary Amendment. In light of this, any rejections directed to cancelled claims 3 and 5 are moot.

New dependent claim 8 was added to further define specific therapeutic agents, (i.e., anti-inflammatory, non-steroidal anti-inflammatory drugs (NSAIDs), beta adrenergic and anti-infective agents) as defined in independent pharmaceutical composition claim 6, from which new claim 8 depends.

Applicants also have made amendments to the claims in the interest of advancing prosecution, i.e., to correct for inadvertent typographical, grammatical errors and/or informalities, such as claim dependencies or antecedent basis issues.

No new matter has been added to the claims or specification of the above-identified application.

Applicants request consideration and entry into the record of the following amendments and remarks.

#### **Rejection Under 35 U.S.C. §112, 1<sup>st</sup> and 2<sup>nd</sup> paragraphs**

Claims 1 and 4-7 are rejected under 35 U.S.C. §112, 1<sup>st</sup> and 2<sup>nd</sup> paras., as set forth below.

While the Examiner has rejected claims 3 and 5 as indicated above, applicants respectfully reiterate that claims 3 and 5 were cancelled in the Preliminary Amendment filed December 16, 2005. In light of this, any rejections directed to cancelled claims 3 and 5 are moot.

Claims 1, 4 and 6-7 are rejected under 35 U.S.C. §112, 1<sup>st</sup> para., for failure to comply with the enablement requirement.

Claims 1 and 7 are rejected under 35 U.S.C. §112, 1<sup>st</sup> para., for failure to comply with the enablement requirement as "the claim(s) contain subject matter, which was not described in the specification in such a way as to enable one skilled in the art . . . to make and/or use the invention specification". The Examiner states that the "the structural examples disclosed show compounds where Z is a bond or O . . . R1 and Q

are exemplified as a 6-membered aryl. There is no showing how to make and use other variances of these substituents within the scope set forth in claims 1 and 2.”

To advance prosecution and obviate the above-identified rejection, applicants have cancelled claim 1 and amended claim 2 to be an independent claim. Claim 7 has been amended to be dependent upon amended claim 2.

Claims 4 and 6 are rejected under 35 U.S.C. §112, 1<sup>st</sup> para., as the specification while enabling for the process of making novel chemical compounds, as described on pages 1-10 of the instant specification, does not reasonably provide enablement for the use of any such compounds, as suggested by the breadth of the instant claims to be employed in the treatment of a human or animal of the instant invention.

Applicants have amended claim 4 to recite specific autoimmune disorders or inflammatory conditions as supported by the instant specification at page 11, lines 1-32 and 34-35. Further claim 6 has been amended to depend from amended claim 4.

Claims 4 and 6 are rejected under 35 U.S.C. §112, 2<sup>nd</sup> para., for indefiniteness and failure to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

The Examiner has stated that claim 4 recites “a treatment that is “susceptible to” “any immune disorder or any inflammatory condition” using recited Formula (I)” and that “it is unclear whether applicants’ intent is to recite a population of human or animal . . . and a reference to a condition or conditions to be treated.”

Applicants have amended claim 4 to recite specific diseases that are treatable by compounds of the present invention and as administered to a human or a animal subject as supported by the above-identified specification. Amended claim 4 recites:

“A method for treatment of a human or animal subject with an autoimmune disorder or an inflammatory condition, which comprises administering to said human or animal subject an effective amount of a compound claim 2, wherein: the autoimmune disorder or inflammatory condition is selected from . . . [specific diseases are listed in claim 4].”

In particular, the Examiner states that it is unclear “which singular or multiple additional agents will be included in the composition” as “additional therapeutic agents” are not pointed out in claim 6.

Applicants have amended claim 6 to recite a pharmaceutical composition, which comprises one or more pharmaceutically acceptable carriers or diluents (amendment supported by the above-identified specification at page 12, lines 14-21) and specific therapeutic agents (as defined in the specification at page 14, lines 1-8). Amended claim 6 recites:

"A pharmaceutical composition comprising a compound of claim 2, pharmaceutically acceptable carriers or diluents and optionally one or more other therapeutic agents selected from anti-inflammatory agents, NSAIDs, beta adrenergic agents or antiinfective agents".

New claim 8 dependent from amended claim 6, further recites specific types of anti-inflammatory agents, NSAIDs, beta adrenergic agents or antiinfective agents.

In each of the above-identified amendments, no new matter has been added to the claims of the present application.

In light of the above, applicant requests that the above-identified rejections under 35 U.S.C. § 112, 1<sup>st</sup> and 2<sup>nd</sup> paragraphs, be withdrawn.

**Allowable Subject Matter**

Claim 2 is objected to and indicated as allowable if rewritten in independent form to include all limitations of the base and any intervening claims.

Applicants request that the above-identified rejection be held in abeyance until the determination of patentable subject matter.

**CONCLUSION**

In view of the above amendments and remarks, applicants believe that the claims of the present application are in condition for allowance and is earnestly solicited.

If any additional fees or charges are required authorization is hereby granted to charge any necessary fees to Deposit Account No. 19-2570 accordingly.

Should the Examiner have any questions or wish to discuss any aspect of this case, the Examiner is encouraged to call the undersigned attorney at the number below.

Respectfully submitted,



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